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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/359,937 12/20/94 ILLUM

L EPC148C1

EXAMINER

KISHORE, G

15M1/0317

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ART UNIT

PAPER NUMBER

1502

DATE MAILED:

03/17/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3- month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-14 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-14 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,204,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant limitations of the microsphere sizes and percentages are deemed to be included in the generic language in claims of said patent.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Sarett*, 327 F2d 1005, 140 USPQ 474 (CCPA 1964); *In re Schneller*, 397 F2d 350, 158 USPQ 210 (CCPA 1968); *In re White*, 405 F2d 904, 160 USPQ 644 (CCPA 1969); *In re Thorington*, 418 F2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F2d 686 F2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F2d 887, 225 USPQ 645 (Fed. Cir. 985); and *In re Goodman*, 29 USPQ F2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Claims 11-14 are rejected under judicially created doctrine of double patenting.

The subject matter recited in claims 11-14 is fully disclosed in the patent. The claims of the application, if allowed, would not only provide protection to the nominal system and method, but would also extend patent coverage to the drug containing microspheres already disclosed and covered by the claims in the patent. Thus, the controlling fact is that patent protection for the device and method, fully disclosed in and covered by the claims of the patent, would be extended by the allowance of the claims in the application.

Furthermore, there is no apparent reason why applicant was prevented from presenting the claims in the application for examination during the prosecution of the issued patent.

Claims 1-2 and 5-14 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to microspheres made of material in claim 3. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Applicant has not adequately taught what others besides those recited in claim 3 possess bioadhesive properties and could be used in practicing this invention.

Claims 3-4, 6 and 8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"derivatives" in claim 3 is still deemed to be indefinite. A case law regarding this term have already been cited by the examiner.

Does applicant mean crosslinking by the expression used in claim 6? Heat is known to crosslink collagen for e.g.

The specific compounds in claim 8 are deemed to be included in "surfactant" which is also recited.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 11 and 13 are rejected under 35 U.S.C. § 102(e) as being anticipated by Illum 4,847,091 of record.

Illum discloses the same invention. (Note the abstract; column 1, lines 15-48; examples and claims).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 are rejected under 35 U.S.C. § 103 as being unpatentable over Illum, 1986 of record.

Illum (1986) discloses albumin starch microspheres which could be used to deliver drugs including peptides and proteins to the nasal mucosa. She further discloses that the microspheres could be modified by crosslinking (note the discussion section on page 207). According to Illum such a system would ensure an increased time of contact between the delivery system and the mucosa by a process of broadhesion with the possibility of additionally releasing the drug from the system in a sustained and controlled manner (note the 23rd paragraph on page 206). The important factors including the particle sizes are also disclosed by Illum (pages 206-207). Pump spray is disclosed on page 208.

Although Illum's teachings do not include the use of penetration enhancers, her disclosure include the knowledged in the art of the use of such enhancers for nasal (mucosal) delivery of proteins (see 3rd paragraph, introduction). The instant invention is deemed to be an obvious extension of Illum. The criticality of the limitation in claim 12 is not readily apparent to the examiner.

Claims 7-12 and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Illum 4,847,091 or Illum (1986) in view of Hansen et al. or Salzman et al. and vice versa.

Illum 4,847,091 does not teach penetration enhancers.

Illum (1986) although teaches the awareness in the art of penetration enhancers, does not use these enhancers in the microspheres.

Hansen et al. disclose that biological response to nasal administration of calcitonin could be increased by inclusion of various surfactant in the formulation (see "conclusions" on page 241) Hansen et al.'s. disclosure does not include the use of microspheres. An artisan could, however, interpret Hansen et al.'s disclosure, however does not include microspheres.

Salzman et al. disclose that intranasal administration of insulin in combination with a non-ionic detergent increases the absorption of insulin (note discussion on page 1081). Salzman et al.'s term "formulations" as inclusive of microspheres.

To include penetration enhancers such as surfactant taught by Hansen et al. or Salzman et al. in the microspheres of Illum or Suzuki et al. (assuming phospholipids are not penetration enhancers) for nasal delivery for drugs including insulin would have been obvious to one of ordinary skill in the art the time the invention was made since such an inclusion would certainly increase the absorption of drugs by mucosal membrane.

Alternatively, to use the microspheres of starch or similar swellable and broadhesive material as taught by Illum (1986) Illum (4,847,091) in the teachings of Hansen et al. or Salzman et al. would have been obvious to one of ordinary skill in the art since such spheres adhere to the nasal and allow the drug to be release in a sustained manner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to G.S. Kishore, whose telephone number is (703) 308-2440. The examiner can normally be reached on Monday-Thursday from 6:30a.m.

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Art Unit: 1502

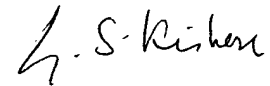
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to 4:00p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-3596.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

Kishore:css
March 8, 1995
March 14, 1995



Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500